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CDC Accepts ACIP Recommendations Regarding Smallpox Vaccination and Cardiac Events and Distributes Revised Pre-Vaccination Education Materials

The ACIP held an emergency meeting by conference call on Friday, March 28, 2003, to make recommendations to CDC regarding cases of cardiac adverse events that have been reported following smallpox vaccination, including myocarditis and/or pericarditis, myocardial infarction, and angina.

The available data suggest that smallpox vaccine can cause myocarditis and/or pericarditis. However, the number of cases of angina and myocardial infarction reported are compatible with the expected background rate. This means that observed angina and heart attack cases may have a coincidental rather than a causal relation to the vaccine. Nevertheless, as a precautionary measure, it is prudent to defer vaccination at this time of persons most at risk for heart attacks and angina, independent of vaccination.

Therefore, the ACIP recommended that persons be excluded from the pre-event smallpox vaccination program who have been diagnosed as having a heart condition or ischemic cardiovascular condition, with or without symptoms (such as previous myocardial infarction, angina, congestive heart failure, cardiomyopathy, stroke or transient ischemic attack, or other heart conditions under the care of a doctor). The Committee also recommended that persons be excluded if they have three or more known major cardiac risk factors including hypertension, diabetes, hypercholesterolemia, and smoking. After consulting with experts in cardiology, CDC added to this the additional risk factor of having an immediate family member who has had onset of a heart condition before age 50. The Committee supported including the risk factors in pre-vaccination clinic education materials, so potential vaccinees could evaluate their risk status with their personal physician prior to presentation for vaccination if they had concerns; at the vaccination clinic, verbal screening for known risk factors was recommended.

The Committee did not recommend special medical follow-up for persons with cardiovascular risk factors who had been vaccinated. Persons with risk factors or known atherosclerotic coronary artery disease should be cared for by their physicians in accordance with standard guidelines for treatment and control of these conditions.

CDC has accepted the ACIP recommendations and has revised and distributed fact sheets and pre-vaccination clinic education and screening materials that reflect the new exclusion criteria. These revised forms, dated March 31 2003, replace previously distributed versions and should be used immediately in smallpox vaccination clinics. The materials are available at www.cdc.gov/smallpox.

Background

There is evidence suggesting that smallpox vaccination may cause cases of heart inflammation (myocarditis), inflammation of the membrane covering the heart (pericarditis), and a combination of these two problems (myopericarditis). Most reported cases have occurred in military personnel, who received more than 350,000 doses of smallpox vaccine since December 13, 2002. Overall, military personnel experienced a rate of myopericarditis of approximately 1 per 20,000 primary vaccinated persons (i.e., people vaccinated for the first time). This rate is much higher than expected based on historical data and experience. There have been no cases in military people who had previously received the smallpox vaccine. Cases, aged 21 to 33 years, ranged from mild (no ECG or echocardiogram changes) to severe (transient heart failure), with onset 7 to 19 days after vaccination. They all survived. The newest case is still in the hospital as of March 31, 2003. The others have been discharged from hospital, and have either returned to duty or are on short-term convalescent leave to regain their strength.

In the civilian smallpox vaccination program, as of March 21, 2003, 25,645 persons had been vaccinated. One case of myocarditis and 2 cases of pericarditis have been reported to date. Patients were 45, 45, and 56 years of age, and two were reported to be revaccinees; the vaccination status of the other patient is unknown. Dates of onset were 2 days, 12 days, and 17 days following vaccination; the patient with onset at 2 days had some symptoms prior to vaccination.

As of March 30, 2003, six ischemic (e.g., heart attacks or angina) events - 4 heart attacks and 2 cases of angina - have been reported among civilian vaccinees within 3 weeks of vaccination. Two of the heart attacks presented as out-of-hospital cardiac arrests, and both patients died. Patients ranged in age from 43 to 69 years; all but one were 54 years of age or older. All but one patient had known cardiac risk factors; four are known to have three or more risk factors, and thus would have been excluded from vaccination by the ACIP's new recommendations for pre-vaccination screening (we are still awaiting clinical information on the most recently reported case, and it is possible that that case would have been excluded as well). Additionally, a 55 year old military vaccinee died following vaccination. Autopsy showed a prior myocardial infarction, three-vessel coronary artery disease, and left ventricular hypertrophy. Histopathology revealed evidence of no myo-pericarditis in this man.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES